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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/593,202 | 07/25/2007 | Larry R. Rohrschneider | FHCC:016US/ 10611971 | 5927 |
| 32425 7590 06/23/2010 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701 | | | EXAMINER WILSON, MICHAEL C | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/593,202 | Applicant(s) ROHRSCHEIDER, LARRY R. | |
| | Examiner Michael C. Wilson | Art Unit 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-10,15,17-23,29-35,37,39,40,45-48 and 50-56 is/are pending in the application.
- 4a) Of the above claim(s) 45-48 and 50-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-10,15,17-23,29-35,37,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2-5, 11-14, 16, 24-28, 36, 38, 41-44, 49 and 57-76 have been canceled.
Claims 1, 6-10, 15, 17-23, 29-35, 37, 39, 40, 45-48 and 50-56 remain pending.

Election/Restrictions

The species election has been withdrawn in view of the amendment because the claims all relate to nucleotides 54755-55810 of SEQ ID NO: 1 – a 0.96 kb fragment.

This application contains claims 45-48, 50-56 drawn to an invention nonelected with traverse in the reply filed on 4-17-09. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 6-10, 15, 17-23, 29-35, 37 and 39 are under consideration as they relate to the claims as amended, which all relate to nucleotides 54755-55810 of SEQ ID NO: 1 – a 0.96 kb fragment.

Applicant's arguments filed 4-30-10 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The title will have to be changed to more closely reflect the subject matter being examined.

Claim Rejections - 35 USC § 112

The rejection of claims 1, 6-10, 15, 17-23, 29-35, 37, 39 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn in view of the amendment (the claims all relate to nucleotides 54755-55810 of SEQ ID NO: 1 – a 0.96 kb fragment) and in view of pg 73, lines 23-26, which teaches the .96 kb fragment caused GFP expression.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation of “i) nucleotides 54807 to 61006 but lacking nucleotides 57109 to 57944 or 2)...” in claim 8 is new matter. The specification teaches 54807-47110 and 57945-61006 which would be --nucleotides 54807 to 61006 but lacking nucleotides 57111 to 57944--. In addition, use of “i)” in combination with “2)” is inconsistent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite because "the s-ship gene" does not clearly refer back to the "s-ship gene or a portion thereof". As such, it appears that only the "s-ship gene" is disrupted by the marker sequence, when in fact the "s-ship gene or the portion thereof" must be disrupted by the marker sequence. The claim does not clearly set forth the marker sequence disrupts the s-ship gene OR the portion thereof.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 10 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 9. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 15, 17-21, 23 and 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Birren (AC102564 in GenEmbl database, Nov. 23, 2001).

Birren taught a nucleic acid sequence encoding nucleotides 54755-55810 of SEQ ID NO: 1 (see 6th hit of AC102564 in GenEmbl database, filed by direct submission on Nov. 23, 2001, Whitehead institute/MIT Center for Genome Research). Claim 1 has been included because "heterologous" is a relative term, and the nucleic acid sequence is "heterologous" to many other nucleic acid sequences. Claim 15 has been included because any sequence can be a marker sequence and because the claim is indefinite. Claims 17 and 18 have been included because nucleotides 54755-55810 appear to be constitutive and inducible/conditional as claimed. Claim 19 has been included the nucleic acid sequence can be considered an expression cassette and because "heterologous" is a relative term, and the nucleic acid sequence is "heterologous" to many other nucleic acid sequences. Claim 21 has been included because the coding region is a reporter gene. Claim 23 has been included because the coding region can be considered therapeutic/diagnostic. Claim 29 has been included because the sequence can be considered a vector. claim 32 has been included because "heterologous" is a relative term, and the nucleic acid sequence is "heterologous" to many other nucleic acid sequences.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 15, 17-23, 29-35, 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birren (cited above) in view of Alt (US Patent 5,583,278).

Alt taught embryonic stem cells with a plasmid comprising nucleic acid sequence encoding a heterologous protein operably linked to a promoter. The coding region of the protein is modified by inserting a marker protein (col. 10, lines 8-24). Alt did not teach the promoter was the s-ship promoter claimed.

However, the s-ship promoter was disclosed by Birren.

Thus, it would have been obvious to those of ordinary skill in the art at the time the invention was made to transfect embryonic stem cells with a plasmid comprising nucleic acid sequence encoding a heterologous protein operably linked to a promoter as taught by Birren, wherein the promoter was the s-ship promoter disclosed by Birren.

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Those of ordinary skill in the art at the time of filing would have been motivated to use the s-ship promoter as the promoter to express the protein in ES cells.

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

Claims 1, 15, 17-23, 29-35, 37, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birren (cited above) in view of Cooke (US Patent 5,428,070).

Cooke taught hematopoietic stem cells with a plasmid comprising nucleic acid sequence encoding a heterologous protein operably linked to a promoter. The coding region of the protein is modified by inserting a marker protein (col. 6, lines 33-55). Alt did not teach the promoter was the s-ship promoter claimed.

However, the s-ship promoter was disclosed by Birren.

Thus, it would have been obvious to those of ordinary skill in the art at the time the invention was made to transfect hematopoietic stem cells with a plasmid comprising nucleic acid sequence encoding a heterologous protein operably linked to a promoter as taught by Birren, wherein the promoter was the s-ship promoter disclosed by Birren. Those of ordinary skill in the art at the time of filing would have been motivated to use the s-ship promoter as the promoter to express the protein in ES cells.

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

Applicants have received a search for 3 segments of the 11.5 kb fragment and a search for the 9.6 kb fragment. The fragments listed in claims 6-10 have not been searched. It is unclear at this time whether claims 6-10 are free of the prior art.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

SEQ ID NO: 1 of Krystal (US Patent 6,218,162), starting at nucleotide 800, is the same as nucleotides 55668-55810 of SEQ ID NO: 1.

Lucas (Blood, 1999, Vol. 93, No. 6, pg 1922-1933) also taught nucleotides 55668-55810 of SEQ ID NO: 1.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday through Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Primary Patent Examiner